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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/389,565	09/03/1999	DAVID M. NEVILLE, JR.	14028.0290	5574

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/389,565

Applicant(s)

NEVILLE, JR. ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-33, 37-39 and 43-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37 and 44-47 is/are allowed.
- 6) ☒ Claim(s) 30-33, 38, 39, 43 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1644

DETAILED ACTION

1. Claims 30-33, 37-39, 43-47, and newly added Claim 48, are pending and being acted upon.

2. Applicant's amendment and remarks, filed 4/18/05, are acknowledged. In view of Applicant's amendment, the previous rejection of Claim 45 for the recitation of "about 152 or 145 carboxy terminal amino acid residues ..." has been withdrawn.

3. In view of the new rejections set forth below, this action has not been made final.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 30, 38, 39, and 43 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) In Claim 30, a fusion immunotoxin comprising ... a diphtheria toxin moiety ... wherein 152-145 carboxy terminal amino acid residues are truncated from the native diphtheria toxin moiety, and,

B) In Claims 38 and 43, a method for inhibiting rejection of transplanted tissue or organs in a subject, are not supported by the specification.

Regarding A), Applicant argues that the disclosure of mutants DT390, DT383, and MSPA5 support the claim. Applicant further argues that these mutants represent both ends of the claimed range as well as an example with the range. Applicant argues that the claimed intermediate truncations would have the

Art Unit: 1644

same function as the disclosed species and that they are not unpredictable. Applicant further argues that each species within the claimed range need not be described.

First note that Applicant's arguments regarding function and unpredictability are not relevant to the instant rejection. The instant rejection is not for lack of enablement, but rather for lack of adequate written description. Regarding the rejection for lack of adequate written description, if Applicant had chosen to disclose the claimed range in the instant specification there would be no rejection here. The fact that Applicant disclosed 3 of the 8 species that would fall within the claimed range does not demonstrate that Applicant envisioned the entire range, and all of the species within it, at the time of filing.

It is the Examiner's position that it is well-established that the requirement of the first paragraph of 35 U.S.C. 112 is not satisfied by subject matter that is not disclosed, but might be obvious. One shows possession of an invention by describing the invention, including all claimed limitations. *Lockwood v. American Airlines*, 1966, 41 USPQ2d 1961 (CAFC 1997), makes clear "all the limitations must appear in the specification".

Regarding B), Applicant argues that support for "inhibiting rejection of transplanted tissue or organs" can be found at page 31, lines 17-19; page 32, lines 19-26; page 40, lines 3-7; and page 39, lines 33-35 of the specification.

A review of the specification shows that 3 of the cites concern allo-skin grafts in monkeys, and the other cite concerns "mismatched" kidney transplants.

It is the Examiner's position that these minimal disclosures do not adequately describe the entire genus of transplanted tissue or organs for which rejection might be inhibited. The claims encompass the inhibition of rejection in any species, while only rhesus monkey is disclosed, and any type of tissue or organ, while only skin and kidney are disclosed, and then only minimally. For example, the cite at page 40 of the specification discloses only, "FN18-CRM9 has also been used as an adjunct in inducing tolerance to mismatched kidney transplants (24)". Reference 24, Parlevliet et al., 1992, comprises a review of the use of OKT3 (not the antibody of the instant claims or specification) for the inhibition of kidney

Art Unit: 1644

rejection. This disclosure cannot be considered even adequate for the use of the scFv antibody of the claims in methods of inhibiting kidney transplantation alone, much less for the inhibition of rejection in all of the other tissue and organ types encompassed by the claims.

6. The following are new grounds of rejection necessitated by Applicant's amendment.

7. Claims 32, 33, and 48 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) The "optional linker" of Claims 32 and 33 is not disclosed in the specification.

B) The immunotoxin of Claim 48 comprising a "truncated toxin moiety not recognized by inhibitory anti-diphtheria toxin antibodies" is not disclosed in the specification.

Regarding A), in the remarks of 4/20/00, Applicant indicates that support for the limitation can be found at page 66 and in Figures 13, 15, and 17 of the specification. The cited disclosures do not teach optional linkers in the scFv of the instant claims

Regarding B), Applicant indicates that support for the new amendment can be found in original Claims 1 and 3 and at pages 40, 48, and 49 of the specification. None of these cites teach the limitation set forth above in the context of the scFv of the instant claim. Page 40 discloses that a truncation mutant was made, and pages 48 and 49 disclose MSPΔ⁵ and a DT-390 construct, respectively. No generic scFv as set forth in the rejection above is disclosed.


8. Claims 37 and 44-47 are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The

Art Unit: 1644

examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

10. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.


6/27/05
G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600